

JUN 13 2011

## 510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

### Submission Information

Contact: Seayoung Ahn  
7612 Barnum Road, Bethesda, MD 20817 USA  
Sponsor: 34-6 Keumam-ri, Seotan-myeon, Pyeongtaek,  
Gyeonggi-do, 451-852, Republic of Korea  
Date Prepared: February 28, 2011  
Tel No: +82-31-664-4101 x110

### Device Identification

Trade Name: 4CIS® SOLAR Spine System and  
4CIS® APOLLON Spine System  
Common Name: Pedicle Screw Spinal Fixation System  
Classification Name: Spondylolisthesis Spinal Fixation Device System(MNH)  
per 21 CFR § 888.3070,  
Spinal Pedicle Screw(MNI) per 21 CFR § 888.3070

### Substantially Equivalent Predicate Devices

The subject devices, 4CIS® SOLAR Spine System and 4CIS® APOLLON Spine System, are substantially equivalent in function, design, composition, material and intended used to: Global Spinal Fixation System(K001668) and OPTIMA™, Spinal System(K031585).

### Device Description

The 4CIS® SOLAR Spine System and 4CIS® APOLLON Spine System are a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, nuts, and a transverse (cross) linking mechanism.

The 4CIS® SOLAR Spine System and 4CIS® APOLLON Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. 4CIS® SOLAR Spine System and 4CIS® APOLLON Spine System implant components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these

implants are available. Specialized instruments are available for the application and removal of the 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System.

### **Indications for Use**

The 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

### **Performance Data and Test Method**

Mechanical testing has been carried out as listed in **APPENDIX 10** which includes the static compression test and static torsion test as well as the dynamic compressive fatigue testing in accordance with ASTM F1717 demonstrates equivalence to the above predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JUN 13 2011

Solco Biomedical Co., Ltd.  
% Solco USA, Inc.  
Mr. Saeyoung Ahn  
7612 Barnum Road  
Bethesda, Maryland 20817

Re: K102458

Trade/Device Name: 4CIS® SOLAR Spine System and 4CIS® APOLLON Spine System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: June 3, 2011  
Received: June 7, 2011

Dear Mr. Ahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

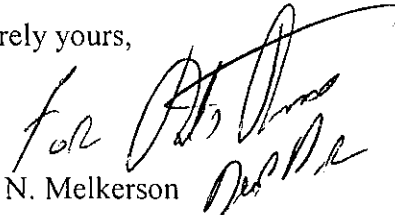
Page 2 – Mr. Saeyoung Ahn

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K102458

Device Name: 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System

### Indications for Use:

The 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System are a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the 4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Prescription Use   X  

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use           

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102458

Solco Biomedical Co., Ltd

4CIS<sup>®</sup> SOLAR Spine System and 4CIS<sup>®</sup> APOLLON Spine System 510(k) Submission